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| 09/910,639 | 07/20/2001 | Daniel A. Vallera | 09531-023001 / Z01015 | 2607 |

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| EXAMINER |
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JONES, DAMERON LEVEST

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| ART UNIT | PAPER NUMBER |
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1616

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/910,639

Applicant(s)

VALLERA ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 23-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-17, 19, 25 and 30-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 20, 21, 23, 24, 26-29 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the following: (1) the acceptable RCE filed 5/26/04; (2) the amendment filed 4/19/04 wherein the status of the claims is as follows: claims 1-17, 19, claims 30-39 are withdrawn; claim 18 is amended; claim 22 is canceled; and claim 40 is added.

Note: Claims 1-21 and 23-40 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments filed 4/19/04 to the rejection of claims 18, 20, 21, 23, 24, and 26-29 made by the Examiner under 35 USC 103 have been fully considered and deemed moot for in view of the rejection below. The rejection of the claims under 35 USC 112 has been considered and found persuasive because Applicant has amended the claims to overcome the rejection.

WITHDRAWN CLAIMS

3. Claims 1-17, 19, 25, and 30-39 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

CLARIFICATION OF THE RECORD

4. It is duly noted that in regards to the previous documents (i.e., Vallera et al) cited in the rejection, Applicant asserted that the reference was directed to normal subjects not those with cancer as required by the instant invention.

For clarification of the record, the claims are directed to a subject suspected of having a cancer, not a subject with cancer. Thus, one suspected of having cancer and testing indicates that cancer is absent in the subject may be considered as a normal subject. However, if the claims were written such that they were directed to a subject with cancer, then Applicant's position arguments would be considered in a different perspective as they relate to the claims.

112 REJECTIONS (Second Paragraph)

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24: The claim as written is confusing because it depends on canceled claim 22.

103 REJECTION

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. Claims 18, 20, 21, 23, 26-29, and 40 rejected under 35 U.S.C. 103(a) as being unpatentable over Pastan et al (US Patent No. 5,990,296).

Pastan et al disclose single chain Fv regions of the monoclonal antibody and uses thereof (see entire documents, especially, abstract). The tumor specific antibody fragments may incorporate fragments such as immunotoxins which have tumor specificity and which may be used to treat cancer (column 1, lines 13-20; column 2, lines 51-59; columns 10-11, bridging paragraph). In addition, Pastan et al disclose a method of killing or inhibition the growth of cells bearing a Lewis^Y antigen wherein the subject is administered a pharmaceutical composition comprising a fusion protein (column 3, lines 50-55). The effector molecule (targeting agent) may be diphtheria toxin (column 9, lines 8-18). The antibody may be joined to the effector molecule (column 9, lines 50-62). The term 'diphtheria toxin' (DT) encompasses the full length native DT or a DT that has been modified (column 10, lines 16-38). The antibody may be conjugated to various labels to produce a highly specific detectable marker that may be used to detect the presence or absence of cells or tissues bearing the particular molecule to which the antibody is detected (column 11, lines 4-11). The antibodies may be derived from monoclonal antibodies designated as B1, B3, and B5 which have been shown to specifically bind carbohydrate antigens that are typically found on various carcinomas including carcinomas of the breast, colon, cervix, and prostate (column 11, lines 57-62; column 18, lines 56-68; column 20, lines 38-50). Labels may be conjugated to the antibody either directly or through a linking molecule. Detection of the antibody bound label depends on type of label (spectroscopic, photochemical, biochemical,

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immunochemical) attached (column 19, lines 20-37). While Pastan et al disclose a method of delivering a immunotoxin composition to a subject, the reference does not disclose various possible labels as set forth in claim 29, for example.

Goldenberg discloses the detection, imaging, and treatment of infections using immunoconjugates comprising an antibody conjugate (see entire document, especially, abstract). The immunoconjugates comprise an immunoreactive component having at least one substantially monospecific antibody or antibody fragment conjugated to at least one diagnostic or therapeutic agent, wherein the antibody or antibody fragment binds to an epitope of the pathogen or of a pathogen-associated antigen (column 2, lines 47-55). The immunoconjugates are also effective diagnostic agents for scintigraphic imaging or magnetic resonance imaging (column 3, lines 59-64). The imaging agent may comprise a bispecific, trispecific, or polyspecific antibody/antibody fragment conjugates that optionally comprise an imaging radioisotope or paramagnetic species (column 4, lines 62-66). The immunoconjugates may be labeled with metals such as Dy, Gd, or Mn to name a few (column 11, lines 6-23; column 18, lines 17-25).

It would have been obvious to one of ordinary skill in the art to modify the invention of Pastan et al using the teachings of Goldenberg and generate a method of delivering a radiolabeled immunotoxin to a subject because Pastan et al disclose immunotoxins that may be radiolabeled which have tumor specificity and may be used in the treatment of mammalian cancer. Goldenberg is cited to illustrate that various radiolabels may be attached to the immunoconjugate for imaging and other purposes. Since both Goldenberg and Pastan et al are directed to immunotoxins that may be

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radiolabeled, the references may be considered to be within the same field of endeavor.

Thus, the references are combinable.

SEARCH COMMENTS


9. It is once again noted that Applicant's elected species is allowable over the prior art of record (elected species: toxic domain is diphtheria toxin; targeting molecule is Her-2/Neu; and the radionuclide species is ^{64}Cu). The search has been expanded to the conditions wherein the toxic domain is diphtheria toxin; any radionuclide; and sFv of the monoclonal antibody B3. The search was not further expanded since prior art was found which could be used to reject the claims.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
Art Unit 1616

July 19, 2004